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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/934,297 | 08/21/2001 | Jennifer E. Van Eyk | PTQ-0037 | 8294 |

26259 7590 09/29/2003
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| EXAMINER |
| LAM, ANN Y |

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| ART UNIT | PAPER NUMBER |
| 1641 | |

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/934,297

Applicant(s)

VAN EYK ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply****A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-28 is/are pending in the application.

 4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) ____ is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

 * See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____ .

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . 6) Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a method of separating a mixture of proteins in a biological sample, classified in class 436, subclass 516.
- II. Claim 9, drawn to a kit for separating a mixture of proteins in a biological sample, classified in class 435, subclass 4.
- III. Claims 10-15, drawn to a method of assessing cellular injury in a subject, classified in class 436, subclass 8.
- IV. Claims 16-17, drawn to a method of profiling proteins in a biological sample, classified in class 436, subclass 15.
- V. Claims 18-22, drawn to a method for detecting myocardial damage in a subject, classified in class 436, subclass 16.
- VI. Claims 23-28, drawn to a method for assessing severity of skeletal muscle damage in a subject, classified in class 436, subclass 63.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I, III, IV, V and VI) and II are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

Art Unit: 1641

product can be used in a materially different process of using that product since the product, i.e., the kit, does not include instructions for mixing the sample with the claimed solution at concentrations sufficient to denature albumin in the mixture, nor instructions for characterizing the separated proteins, wherein the characterization is indicative of cellular injury in a subject, nor instructions to produce a profile of proteins in the sample, nor instructions for detecting a myofilament protein, nor instructions for measuring a ratio of two different isoforms of a myofilament protein.

Inventions I, III, IV, V and VI are unrelated to each other, and are patentably distinct and independent inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation. Invention I requires a concentration sufficient to denature albumin in the mixture, whereas the other inventions do not. Invention III requires characterizing the separated proteins, wherein the characterization is indicative of cellular injury in a patient, whereas the other inventions do not. Invention IV requires producing a profile of proteins, whereas the other inventions do not. Invention V requires detecting myocardial damage by detecting a myofilament protein in serum of a subject, whereas the other inventions do not. Invention VI require measuring a ratio of two different isoforms of a myofilament protein in serum of a subject, whereas the other inventions do not.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

A telephone call was made to Kathleen Tyrrell on September 25, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Art Unit: 1641

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/26/13